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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,264	12/03/2001	Laurie H. Glimcher	HUI-040CP	2529
959 7590 04/25/2007 LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			EXAMINER JUEDES, AMY E	
			ART UNIT	PAPER NUMBER
			1644	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/25/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/008,264

Applicant(s)

GLIMCHER ET AL.

Examiner

Amy E. Juedes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/4/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,8-12,50,51,53-55,57,58,61-75,78-84,87,88 and 90-112 is/are pending in the application.
- 4a) Of the above claim(s) 87,88 and 90-112 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,6,8-12,51,53,54,57,61-63,65,66,68-71 and 78-80 is/are allowed.
- 6) ☒ Claim(s) 50, 55, 58, 64, 67, 72-75, and 81-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's amendment and remarks, filed 4/4/07, are acknowledged.

Claims 4 and 89 have been cancelled.

Claims 6, 50-51, 53, 57, 65-66, 90-92, 95, 100, and 102 have been amended.

Claims 1-2, 6, 8-12, 50-51, 53-55, 57-58, 61-75, 78-84, 87-88, and 90-112 are pending.

2. Claims 87-88 and 90-112 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Claims 1-2, 6, 8-12, 50-51, 53-55, 57-58, 61-75, and 78-84 are being acted upon.

4. The rejection of the claims under 35 U.S.C. 112 second paragraph for "modulating" is withdrawn in view of Applicant's amendment to the claims.

5. The rejections of the claims under 35 U.S.C. 112 first paragraph for new matter are withdrawn in view of Applicant's amendment to the claims.

6. The rejections of the claims under 35 U.S.C. 112 first paragraph for lack of written description and enablement are withdrawn in view of Applicant's amendment to recite the function limitation of inducing IFN- γ production in CD4+ cells.

7. The following are new grounds of rejection.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 50, 64, and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50 and 84 recite that the nucleic acid molecule encodes a polypeptide with an activity including inducing IFN- γ production in CD4+ cells and inducing Th1 associated cytokine production. However, claims 50 and 84 depend from claims 6 and

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53, respectively, which are limited to nucleic acid molecules encoding polypeptides which induce IFN- γ production (a Th1 associated cytokine) in CD4+ cells. Thus, the limitation of inducing IFN- γ production in CD4+ cells in claims 50 and 84 is unclear, since it does not further limit the scope of the independent claims. Likewise, the recitation of inducing a Th1 associated cytokine production in claims 50 and 84 renders the claims indefinite, since it actually broadens the scope of the claim already limited to a particular Th1 associated cytokine (IFN- γ).

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 58 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written description to demonstrate that applicant was in possession of the claimed genus of nucleic acids "comprising at least 700 nucleotides which are complementary to at least 700 nucleotides of SEQ ID NO: 1".

The instant claim is drawn to a genus of nucleic acid molecules that comprise at least 700 nucleotides complementary to 700 nucleotides of SEQ ID NO: 1. It is noted that there is no requirement that said complementary nucleotides be contiguous. Since SEQ ID NO: 1 is a nucleic acid molecule comprising approximately 1600 nucleotides, the claims encompass nucleic acid molecules that are less than 50% identical over the entire length of SEQ ID NO: 1 (i.e. complementary over 700 out of 1600 nucleotides). Thus, the claims encompass a wide range of structurally different nucleic acid molecules. Furthermore, the claims do not recite any functional limitations required of the nucleic acid molecules. Furthermore, other than mouse T-bet (SEQ ID NO: 3), the specification does not disclose a single example of nucleic acid molecules that comprise at least 700 nucleotides complementary to SEQ ID NO: 1. The disclosure of a single species is not sufficiently representative of the broad

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range of structurally and functionally different nucleic acids molecules encompassed by the claims. Thus, one of skill in the art would conclude that the specification fails to provide adequate written description to demonstrate that Applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F. 3d 1559, 43, USPQ2d 1398.

11. Claims 55, 58, 67, 72-75, and 81-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification does not enable one of skill in the art to use the invention as broadly claimed.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. With these teachings in mind, an enabling disclosure, commensurate in scope

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with the breadth of the claimed invention, is required.

The instant claims encompass a genus of nucleic acid molecule fragments comprising at least 700 nucleotides of SEQ ID NO: 1. The disclosed use for the claimed nucleic acid molecules relates to their ability to encode a DNA binding protein that is capable of activating IFN- γ transcription. It is known that the DNA binding domain of T-bet protein is encoded by an approximately 600 nucleotide region of SEQ ID NO: 1 (see Szabo et al., Fig. 1, of record). Since the entire T-bet nucleic acid molecule of SEQ ID NO: 1 comprises more than 1600 nucleotides, the instant claims encompass fragments that do not even comprise a DNA binding domain. While the instant specification might enable one of ordinary skill in the art to use a fragment of a T-bet nucleic acid molecule that comprises the DNA binding domain, the instant specification does not enable one of skill in the art to use the nucleic acid molecules as broadly claimed.

12. Claims 1-2, 6, 8-12, 51, 53-54, 57, 61-63 65-66, 68-71, and 78-80 are allowed.

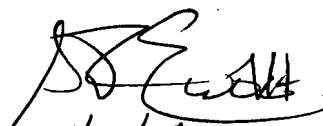
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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4/23/07

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER